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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,084	05/24/2000	Keiya Ozawa	50026/012002	5150

7590

03/11/2003

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EXAMINER

BASI, NIRMAL SINGH

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/577,084**

Applicant(s)  
**Keiya et al**

Examiner  
**Nirmal S. Basi**

Art Unit  
**1646**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jan 23, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-20 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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### DETAILED ACTION

1. The Reply to Restriction Requirement filed 11/14/02 (paper number 13) has been entered.

Upon further consideration the Restriction requirement mailed 9/20/02 (paper number 11)  
5 is withdrawn, and a new restriction follows.

3. *Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, drawn to fusion protein comprising(a) a ligand-binding domain, (b) a  
domain that associates when a ligand binds to the domain of (a), and © a domain  
10 comprising a cytokine receptor or part therefor that imparts proliferation activity to  
a cell upon association, DNA encoding the fusion protein, a vector comprising said  
DNA and cell comprising said vector, classified in class 536, subclass 23.4.

II. Claim 9, drawn to a method for selectively proliferating the cell of claim 8, classified  
in class 435, subclass 7.21.

15 III. Claims 10-18, drawn to a vector comprising a desired exogenous gene and a gene  
encoding a fusion protein comprising(a) a ligand-binding domain, (b) a domain that  
associates when a ligand binds to the domain of (a), and © a domain that imparts  
proliferation activity to a cell upon association and cell comprising said vector,  
classified in class 435, subclass 320.1.

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- IV. Claim 19, drawn to a method for selectively proliferating the cell of claim 18, classified in class 435, subclass 7.21, for example .
- V. Claim 20, drawn to a kit comprising (a) vector of claim 7 and (b) a ligand capable of acting on the "ligand-binding domain" of the fusion protein encoded by the gene contained in the vector, ligand has not been specified, classified in 530, subclass 300.
- 5 VI. Claim 20, drawn to a kit comprising (a) vector of claim 10, and (b) a ligand capable of acting on the "ligand-binding domain" of the fusion protein encoded by the gene contained in the vector, ligand has not been specified, classified in 530, subclass 300.

The inventions are distinct, each from the other because of the following reasons:

10 The products of Inventions I, III, V and VI from each other they have distinct functional, chemical and physical properties and are capable of separate use and manufacture.

The products of Inventions I and V and the methods of Inventions II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products may be used for the production of antibodies of Invention.

15

The products of Inventions III and VI and the methods of Inventions IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

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different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products may be used for the production of antibodies of Invention.

5 The products of invention III and VI are distinct from the methods of Invention II, wherein the products of invention III and VI can neither be used in nor made by the methods of Invention III.

The products of invention I and V are distinct from the methods of Invention IV, wherein the products of invention I and V can neither be used in nor made by the methods of Invention IV.

10 The products of Inventions I-IV and XI are distinct from each other because they have distinct functional, chemical and physical properties and are capable of separate use and manufacture.

15 Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, restriction for examination purposes as indicated is proper. A search of the art for Inventions I-VI would not be co-extensive with each other. Because the searches required for these inventions are not co-extensive an examination of the materially different, patentably distinct inventions in a single application would constitute a serious burden on the examiner.

An election to prosecute one of the groups listed I-VI must be made. Affirmation of this election must be made by applicant in responding to this Office action.

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The application contains claims directed to the following patentably distinct species of the claimed invention:

a cytokine receptor selected from:

1) G-CSF receptor

5                   2) c-mpl

Claims 1 is an example of a generic claim. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds

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one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5 Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

10  
**Advisory Information**


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

15 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

20 Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

25 Nirmal S. Basi  
Art Unit 1646  
March 10, 2003

  
YVONNE EYLER, PH.D.  
SUPERVISORY PATENT EXAMINER  
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